Appl. No.

09/514,999

Filed

February 29, 2000

REMARKS

Claims 2-8, 12, and 14-15 have been amended to clarify the invention. Exemplary support for the amendments can be found in Examples 1-3 on pages 8-10, for example. No new matter has been presented. Applicant respectfully requests entry of the amendments and reconsideration of the application in view of the amendments and of the following remarks.

Claim Rejections - 35 U.S.C. § 112, first paragraph

Claims 2-8 and 10-15 have been rejected under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement. The Examiner maintains that "there is no clear basis or support in the record for the specific limitations of claim 10 as written."

A patent specification satisfies the written description requirement if it "clearly allow[s] persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." In re Gosteli, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989); see also M.P.E.P. § 2163 ("[A] patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention."). The fact that the exact wording of a claim limitation does not appear in the specification does not mean that the limitation lacks written description support. See Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323, 56 U.S.P.Q.2d 1481, 1483 (Fed. Cir. 2000) ("[T]he disclosure as originally filed does not have to provide in haec verba support for the subject matter at issue.").

To further clarify the invention, Applicant has amended claims 2-8, 12, and 14-15 to recite that the claimed methods employ a "yeast RNA-containing composition." Support for this limitation can be found in the Examples. Examples 1, 2, and 4 teach the use of compositions derived from whole yeast by extraction, physical crushing, or autolysis. "Unwanted components" such as protein were removed from these compositions. See page 8, line 26. However, Example 3 teaches that the claimed method may also employ a commercially-produced "yeast RNA" as a starting material. The use of yeast RNA alone in an example presented as a preferred embodiment of the invention would reasonably convey to one of skill in the art that when the application was filed, the inventors possessed the concept of using in the claimed

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method a composition containing, at a minimum, yeast RNA. Applicant submits that this constitutes written description support for the limitation "yeast RNA-containing composition."

Furthermore, the remainder of the limitations of Claim 10 are similarly supported in the originally-filed specification at a minimum by Examples 1 through 3, each of which independently provides written description support for every limitation of Claim 10 as amended. Specifically, support for the "decomposition step, comprising nuclease digestion or alkali hydrolysis" limitation can be found at: page 8, line 31-page 9, line 2; page 9, lines 24-26; and page 10, lines 14-16. Support for the "increasing the yield of polyamines recovered . . . by approximately 2-3.2 times" limitation can be found at: page 9, lines 11-12; page 10, line 5; and page 10, line 25. Support for the "for approximately 15-18 hours" limitation can be found at: page 9, line 2; page 9, line 26; and page 10, line 15. Support for the "treated in solution with nuclease added in a concentration of approximately 1-2 mg/ml, at approximately 25-37°C, and at a pH of approximately 6-8" limitations can be found at: page 8, line 30- page 9, line 2; and page 9, lines 23-27. Support for the "dissolved in a 0.3 N alkali solution at 37°C" limitation can be found at page 10, lines 14-16. Analogous limitations of the remaining claims are similarly supported.

Applicant also submits that the Tanimoto Declaration filed July 1, 2004, which the Examiner has noted is "directed to RNA of yeast," is directly applicable to the pending claims as amended.

Based on the foregoing, Applicant submits that the claims as amended are fully supported by the originally-filed specification. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of the pending claims based on the first paragraph of 35 U.S.C. § 112.

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CONCLUSION

In light of the Applicant's amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: September 1, 2004 By:

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